

## Actions Taken by FDA Center for Veterinary Medicine

---

The following corrections or additions to the January 2004 list were published in the Federal Register in July 2004.

### New Approvals

---

#### NADA Number: 141-186

Trade Name: SURPASS™  
Ingredients: Diclofenac sodium  
Sponsor: IDEXX Pharmaceuticals, Inc.  
Approval Date: May 13, 2004  
Status: Prescription only  
Route: Topical  
Species: Horse  
Drug Form: Cream  
Concentration: 1% diclofenac sodium  
Indications: For the control of pain and inflammation associated with osteoarthritis (OA) in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock, and pastern) joints.  
Patent number: 4,761,288                      Expiration date: August 2, 2005  
                    4,897,269                      January 30, 2007  
                    4,937,078                      June 26, 2007  
Exclusivity: 5 years

21CFR 524.590

#### NADA Number: 141-235

Trade Name: Excede™ For Swine  
Ingredients: Ceftiofur crystalline free acid  
Sponsor: Pharmacia & Upjohn Co.  
Approval Date: June 18, 2004  
Status: Prescription only  
Route: Intramuscular  
Species: Swine  
Drug Form: Liquid (suspension)  
Concentration: 100 milligrams per milliliter  
Indications: For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*.  
Tolerance: 21CFR 556.113 Ceftiofur: The tolerances for residues of desfurioylceftiofur (marker residue) are: kidney (target tissue) 0.25 part per million, liver 3 parts per million, and muscle 2 parts per million.  
Withdrawal: 14 days  
Exclusivity: 3 years

21CFR 522.315 & 556.113

#### ANADA Number: 200-297

Pioneer Product: 140-886  
Trade Name: Ivermectin Chewable Tablets  
Ingredients: Ivermectin  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: June 18, 2004  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Tablet (chewable)  
Concentration: 68 micrograms, 136 micrograms, or 272 micrograms per tablet  
Indications: To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection.

21CFR 520.1193

## Actions Taken by FDA Center for Veterinary Medicine

---

### ANADA Number: 200-310

Pioneer Product: 113-645  
Trade Name: estroPLAN™ Injection  
Ingredients: Cloprostenol sodium  
Sponsor: Parnell Laboratories (Aust) Pty. Ltd.  
Approval Date: May 13, 2004  
Status: Prescription only  
Route: Intramuscular  
Species: Cattle, beef and dairy  
Drug Form: Liquid (solution)  
Concentration: 250 micrograms per milliliter.  
Indications: To induce luteolysis in beef and dairy cattle, terminate pregnancies from mismatings, and to treat certain conditions associated with prolonged luteal function.  
Tolerance: Not required.  
Withdrawal: None

21CFR 522.460 & 510.600

### ANADA Number: 200-372

Pioneer Product: 055-060  
Trade Name: Han-Pen™  
Ingredients: Penicillin G Potassium  
Sponsor: G.C. Hanford Manufacturing Co.  
Approval Date: May 21, 2004  
Status: Over-the-counter  
Route: Oral  
Species: Turkeys  
Drug Form: Powder (soluble)  
Concentration: 0.5 billion units penicillin G potassium per foil bag (313 grams).  
Indications: For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.  
Tolerance: 21CFR 556.510 Penicillin: A tolerance of 0.01 part per million is established for penicillin and the salts of penicillin residues in the uncooked edible tissues of turkeys.  
Withdrawal: One day

21CFR 520.1696b

### ANADA Number: 200-328

Pioneer Product: 124-241  
Trade Name: Oxytocin Injection  
Ingredients: Oxytocin  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: May 21, 2004  
Status: Prescription only  
Route: Intravenous, intramuscular, or subcutaneous  
Species: Horses, mares; cattle, cows; sheep, ewes; swine, sows  
Drug Form: Liquid (solution)  
Concentration: 20 U.S.P. units per milliliter  
Indications: As an aid in the management of parturition in the following ways: precipitate labor; accelerate normal parturition; facilitate postpartum evacuation of uterine debris; facilitate postoperative contraction of the uterus following a cesarean section, and control of uterine hemorrhage. Also serves to contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.  
Tolerance: Not required.  
Withdrawal: None

21CFR 522.1680

## Actions Taken by FDA Center for Veterinary Medicine

---

### Change of Sponsor

---

**NADA Numbers:**     **007-076, 008-244, 043-215, & 092-150**

From:                 PM Resources, Inc.  
To:                    Virbac AH, Inc.  
                          3200 Meacham Blvd.  
                          Ft. Worth, TX 76137  
Drug labeler code: 051311

### Addition of Sponsor

---

Parnell Laboratories (Aust) Pty. LTD.  
Century Estate, Unit 6  
476 Gardeners Rd.  
Alexandria, New South Wales 2015, Australia

Drug Labeler Code: 068504

### Correction of Patent Information

---

**NADA Number:**     **141-035**  
Patent Numbers:     Expiration Dates:  
4,798,837             May 16, 2012  
5,416,102             January 17, 2006

**NADA Number:**     **141-084**  
Patent Number:       Expiration Date:  
5,994,395             February 15, 2016

**NADA Number:**     **141-105**  
Patent Numbers:     Expiration Dates:  
4,798,837             January 17, 2006  
5,416,102             May 16, 2012

**NADA Number:**     **141-175**  
Patent Number:       Expiration Date:  
5,750,548             May 23, 2012

**NADA Number:**     **141-204**  
Patent Numbers:     Expiration Dates:  
5,750,548             May 23, 2012  
5,994,395             February 15, 2016

**NADA Number:**     **141-205**  
Patent Numbers:     Expiration Dates:  
5,750,548             May 23, 2012  
4,798,837             January 17, 2006

## **Actions Taken by FDA Center for Veterinary Medicine**

---

### **Suitability Petition Action**

---

Number: 04P-0175/CP1  
Sponsor: Intervet, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristic(s): The generic product will have a change in strength (concentration) from the pioneer.  
Action: Approved on April 28, 2004.